SARS-CoV-2 Observational Study

Gepubliceerd: 12-04-2020 Laatst bijgewerkt: 18-08-2022

determination course of disease of COVID-19 in the primary care setting

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29166

Bron
Nationaal Trial Register

Verkorte titel
SOS COVID

Aandoening

acute respiratory tract infection

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: The European Commission under H2020 call SC1-PHE-CORONAVIRUS-2020

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The proportion of COVID-19 in patients presenting with CA-ARTI in primary care

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: When a new infection emerges, most detailed information about presentation, management and clinical course is obtained from severe and/or hospitalized cases. This is currently also the case for the COVID-19 pandemic. As a consequence, little information is available from patients with mild and/or undiagnosed SARS-CoV-2 infection. These patients often contact primary care providers, either at the practice or by telephone. There is still much uncertainty about who will develop mild or more severe symptoms upon acquiring the infection and who is at risk of severe complications. We will therefore perform a study in primary care with patients presenting with acute respiratory tract infection in 4-8 European countries.

Objective: To generate information on the presentation and management of patients with community-acquired acute respiratory tract infection in primary care during the COVID-19 pandemic, to determine the proportion of these patients infected with SARS-CoV-2, and risk factors for getting COVID-19 and for a complicated course of COVID-19 disease.

Study design: Observational study with patient follow-up.

Study population: Patients aged one year and older, presenting in primary care (either in person, or phone/video), with symptoms of community-acquired acute respiratory tract infection (CA-ARTI) during the COVID-19 pandemic.

Main study parameters/endpoints: The proportion of patients with SARS-CoV-2 infection in patients presenting with CA-ARTI in primary care settings in various European countries, with description of their course of disease (illness days, non-productive days, complications and death).

Doel van het onderzoek

determination course of disease of COVID-19 in the primary care setting

Onderzoeksopzet

follow-up at day 7 and 28

Onderzoeksproduct en/of interventie

none

Contactpersonen

Publiek

Julius Centrum voor Gezondheidswetenschappen en Eerstelijns Geneeskunde, UMCU
Alike van der Velden

31 88-756 8511

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Male or female aged one year or older;
• Consulting face-to-face, online, or telephoning with symptoms of CA-ARTI (upper and or lower), with symptoms of cough, sore throat and/or rhinitis, or when the GP has another reason to suspect COVID-19;
• Is able and willing to comply with all study requirements;
• Participant or legal guardian(s) of a child is able and willing to give informed consent;
• Availability of a freezer at the practice, patient’s home, or a laboratory location to be reached within 1 hour.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Patients with symptoms of earache only;
• Patients who do not master the national language or are otherwise not able to participate in follow-up procedures;
• Patients who are terminally ill;
• Patients tested positive for SARS-CoV-2 prior to recruitment.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	14-04-2020
Aantal proefpersonen:	600
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	12-04-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8520
CCMO	NL73596.041.20

Resultaten

Samenvatting resultaten
none